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Class Action Over Cephalon Off-Label Claims Tossed

By [Jocelyn Allison](#)

Law360 (October 9, 2009, 2:08 PM EDT) -- [Cephalon Inc.](#) has won dismissal of a putative class action brought by a group of municipal benefit funds over the pharmaceutical company's alleged efforts to market three drugs for uses that did not have regulatory approval.

Judge Mary L. Cooper of the U.S. District Court for the District of New Jersey dismissed the complaint Wednesday after concluding that the plaintiffs had failed to allege the facts needed to support their claims. Part of the case was dismissed without prejudice.

The suit claims Central Regional Employees Benefit Fund and other benefit funds have lost “tens of millions of dollars” because they provided coverage for prescriptions of Provigil, Gabitril and Actiq/Fentora for uses other than those approved by the [U.S. Food and Drug Administration](#).

The funds accuse Pennsylvania-based Cephalon of violations of the New Jersey Consumer Fraud Act, fraudulent concealment and illegal fraud. They seek to represent all governmental entities in the U.S. that paid for the drugs as a result of Cephalon's alleged off-label promotion.

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Judge Cooper, however, found that the plaintiffs could not file suit under the Fraud Act and dismissed that claim with prejudice. She concluded that as third-party payors, the funds could not be considered consumers under the statute, and so cannot sue on that basis.

She dismissed the claims for fraudulent concealment and illegal fraud without prejudice after finding that the plaintiffs left key facts out of the complaint, including who made the transactions at issue and how Cephalon allegedly misrepresented itself.

“Assuming that the plaintiffs intend for Cephalon's alleged off-label marketing and promotion scheme, as described in minimal detail in the complaint, to adequately allege 'fraud' or 'misrepresentations,' it is well-established that 'off-label marketing of an approved drug is itself not inherently fraudulent,’” Judge Cooper wrote.

“Merely alleging that Cephalon marketed the drugs at issue for off-label purposes does not state a claim for fraud,” the judge wrote.

The plaintiffs based their claims on a series of qui tam suits filed in the U.S. District Court for the Eastern District of Pennsylvania in 2003, including three actions brought by former Cephalon sales representatives.

The matter resulted in a \$425 million settlement between Cephalon and the federal government in September 2008. Cephalon agreed to plead guilty to one misdemeanor violation of the U.S. Food, Drug and Cosmetic Act and pay \$50 million in fines and forfeiture.

Cephalon also agreed to pay \$375 million plus interest to settle a separate civil suit accusing the company of violating the False Claims Act in connection with claims that were submitted for the drugs to Medicaid, Medicare and other federal programs.

Judge Cooper said referring to the settlement in the complaint did not satisfy the plaintiffs' burden to plead fraud with specificity,

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nor does such a reference “raise a right to relief above the speculative level.”

Gordon Cooney, a partner with [Morgan Lewis & Bockius LLP](#) and attorney for Cephalon, welcomed the ruling Friday.

“We were pleased with Judge Cooper's opinion, which we believe correctly decided the standing issue,” he said.

“Moreover, off-label prescribing by doctors often constitutes the medical state of the art, and the court correctly recognized that the plaintiffs had failed to plead fraud in the complaint.”

Michael D. Fitzgerald, an attorney for the plaintiffs, said he plans to file an amended complaint addressing the court's concerns regarding the lack of particularity. He said the problem arose because the complaint was initially filed in state court, where the pleading requirements are different.

“We're hopeful that Judge Cooper will see the fact that there is a fraudulent scenario and that she'll also agree with the federal court judge in the Eastern District of Pennsylvania, who found with these same defendants with the same motion made against them that there was sufficient basis for the case to go forward,” Fitzgerald said.

The plaintiffs are represented by the Law Offices of Michael D. Fitzgerald. Cephalon is represented by Morgan Lewis & Bockius LLP.

The case is Central Regional Employees Benefit Fund et al. v. Cephalon Inc. et al., case number 09-cv-03418, in the U.S. District Court for the District of New Jersey.

--Additional reporting by Shannon Henson

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